K970235

June 11, 1997

510 (k) Summary

Manufacturer Identification

Biopro
17 17th Street
Port Huron, MI 48060

Contact person: Cheryl Warsinske

Device Identification

Proprietary Name: Townley Tara All Poly Acetabular Cup

Common Name: Prosthetic, All-polyethylene Acetabular Hip Component

Classification Name and Reference: Hip joint, metal/polymer, semi-constrained resurfacing cemented prosthesis.

The Townley Tara All Poly Acetabular Cup component has been designed for use with the ceramic tara femoral replacement in appropriately indicated patients with severe pain and disability associated with advanced coxarthrosis that may be due to rheumatoid, post-traumatic, or degenerative arthritis. The proposed prosthesis is substantially equivalent to the currently marketed Tara Acetabular Poly Cup manufactured by Depuy. It is designed exclusively for use with cement and only in hips with adequate acetabular bone stock. The primary objective is to provide a stable acetabular component and an associated pain-free total hip replacement.
The predominant design features include:

1) Accommodations for a 43mm, 45mm, and 47mm Tara Femoral component.

2) An outer anchoring surface that provides, concurrently, an even distribution of the cement mantle and optimal cement fixation of the component.

3) Minimum polyethylene thickness of 6.5mm.

Comparison of the Depuy TARA Cup vs. the Tara All Poly Cup

Similarities:

1) Requires cemented fixation
2) Made of UHMW Polyethylene (F648)
3) Indications: A) Rheumatoid, post-traumatic, or degenerative coxarthrosis with severe hip pain and limited joint motion resulting in severe physical disability. B) Adequate residual acetabular bone stock to accommodate/stabilize a cemented implant without the use of metal backing.
4) Contraindications: Excessive post-traumatic or arthropathological bone loss of the acetabulum not amenable to a cemented all polyethylene implant and requiring the support of a metal backed component.

Differences:

1a)Depuy All Poly Tara -I.D. 41mm, 43mm, 45mm, 47mm, 49mm, 51mm, 54mm.
O.D. 49mm, 51mm, 53mm, 55mm, 57mm, 59mm, 62mm.
1b) Tara All Poly- I.D. 43mm, 45mm, 47mm.
O.D. 60mm, 62mm, 64mm, and 66mm.
2a) Depuy All Poly Tara- smooth O.D.
2b) Tara All Poly- O.D. designed with "machined-in" cement-spacing polyethylene protrusions and striations.
3a) Depuy All Poly Tara- designed to mate with Depuy Tara femoral prostheses.
3b) Tara All Poly- designed to mate with Biopro ceramic Tara femoral prostheses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1997

Cheryl L. Warsinske, M.S.
Engineer
Biologically Oriented Prosthetics
17 17th Street
Port Huron, Michigan 48060

Re: K970235
Townley Tara All Poly Acetabular Cup
Regulatory Class: III
Product Code: KXB
Dated: April 21, 1997
Received: May 9, 1997

Dear Ms. Warsinske:

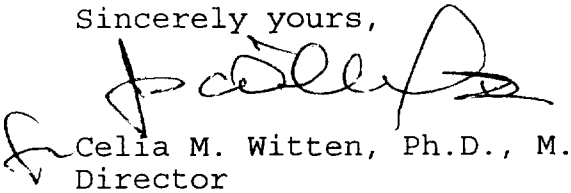
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970235

Device Name: TOWNLEY TARA ALL POLY ACETABULAR CUP

Indications For Use:

1) RHEUMATOID, POST-TRAUMATIC, OR DEGENERATIVE COXARTHROSIS WITH SEVERE HIP PAIN AND LIMITED JOINT MOTION RESULTING IN SEVERE PHYSICAL DISABILITY.

2) ADEQUATE RESIDUAL ACETABULAR BONE STOCK TO ACCOMMODATE / STABILIZE A CEMENTED IMPLANT WITHOUT THE USE OF METAL BACKING.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970235